PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P20069PC00	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/AU2004/001019	International filing date *(day/month/year)* 30 July 2004	Priority date *(day/month/year)* 1 August 2003
International Patent Classification (IPC) or national classification and IPC **Int. Cl.** [7] A61F 2/48		
Applicant VENTRACOR LIMITED et al		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 4 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. [X] *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      - [ ] sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      - [ ] sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

   b. [ ] *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or table related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - [X] Box No. I Basis of the report
   - [ ] Box No. II Priority
   - [ ] Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - [ ] Box No. IV Lack of unity of invention
   - [X] Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - [ ] Box No. VI Certain documents cited
   - [ ] Box No. VII Certain defects in the international application
   - [ ] Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of the report
25 February 2005	4 March 2005
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer **BAYER MITROVIC** Telephone No. (02) 6283 2164

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001019

Box No. I Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This report is based on translations from the original language into the following language , which is the language of a translation furnished for the purposes of:

☐ international search (under Rules 12.3 and 23.1 (b))

☐ publication of the international application (under Rule 12.4)

☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the **elements** of the international application, this report is based on (*replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report*):

☐ the international application as originally filed/furnished

☒ the description:

pages **1, 3-11** as originally filed/furnished
pages* **2** received by this Authority on **25 February 2005** with the letter of **25 February 2005**
pages* received by this Authority on with the letter of

☒ the claims:

pages as originally filed/furnished
pages* as amended (together with any statement) under Article 19
pages* **12** received by this Authority on **25 February 2005** with the letter of **25 February 2005**
pages* received by this Authority on with the letter of

☒ the drawings:

pages **1/10-10/10** as originally filed/furnished
pages* received by this Authority on with the letter of
pages* received by this Authority on with the letter of

☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

☐ the description, pages
☐ the claims, Nos.
☐ the drawings, sheets/figs
☐ the sequence listing (*specify*):
☐ any table(s) related to the sequence listing (*specify*):

* *If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/AU2004/001019

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-8	YES
	Claims		NO
Inventive step (IS)	Claims	1-8	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-8	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1: WO 1999/039769
D2: DE 2730304
D3: US 5995874
D4: US 4679560
D5: US 5741316

Document D1 discloses a system for inducing electrical current/energy transfer into a subcutaneously implanted coil. Embodiment disclosed in Fig.9 comprises an external coils surrounding ferromagnetic core and an implanted coil surrounding its own ferromagnetic core. Ferromagnetic materials are generally conductive. Ferromagnetic cores, although consisting of two separate i.e. mechanically disconnected parts, still form an EMF flux loop and from an electromagnetic point of view both cores could be regarded as one core of the whole system. Coils are inductively coupled, which means that implanted core affects the operation of external coil and vice versa.

Document D2 discloses electrical energy supply system for the body implant having a form of transformer with implanted secondary. An EMF flux loop is formed between the primary and secondary. Each coil is wound onto the half core of ferromagnetic material. Ferromagnetic materials are generally known as conductive materials. Half cores are arranged into a loop like configuration.

Document D3 discloses a transcutaneous energy transfer device consisting of two coupled coils (column 4 lines 16-28). First coil is positioned out of the body, while the second coils implanted under the skin. Second coil surrounds a torus core which could be made of electrically conductive material such as steel or iron (column 8 lines 32-56). An EMF flux loop is established between the two coupled coils and both coils electromagnetically "communicate" with the toroidal core. There is no disclosure that the 1st coil surrounds the portion of the core. However it is considered a common general knowledge to insert a cylindrical ferromagnetic rode in to the 1st coil.

Each of the remaining documents D4 and D5 disclose similar arrangements for transfer of electric power and/or data across the skin surface.

None of the above documents disclose a core which is made from a single piece of magnetic material.

[Continued on supplemental sheet]

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: V

NOVELTY AND INVENTIVE STEP CLAIMS 1-8

As none of the above documents disclose a core which is made from a single piece of magnetic material all claims are novel. It is considered that this feature is also not obvious to a person skilled in the art and, therefore, all claims satisfy requirements for the inventive step.

CLAIMS 1-8 INDUSTRIAL APPLICABILITY

Invention defined in claims 1-8 is industrially applicable.

features in which the lead may to some extent bond or integrate internally with the patient's body. There are many disadvantages with this type of system. One of these disadvantages is that it creates a site on the patient's skin which is open to infection for long periods of time.

As a result, there has been a long felt need for an improved device that conveys power and/or data to an implantable medical device. It is an object of the present invention to address or ameliorate at least one of the above disadvantages.

Brief description of the invention

The present invention provides for a device for communicating electric signals across the skin layer of a patient, wherein said device includes: an electrically conductive core made from a single piece of magnetic material capable of forming an EMF flux loop; first and second coils, which are in EMF communication with said electrical conductive core and wherein said first coil is positioned externally to said patient and surrounds at least a first portion of said electrically conductive core; and said second coil is implanted beneath or in said skin layer and surrounds at least a second portion of said electrically conductive core.

Preferably, said electrically conductively core is implanted at least partially within said skin layer and said electrically conductively core may be formed in a loop or ring-like configuration. The electrically conductively core may not breach an outer surface of said skin layer.

The electrically conductive core may also be encapsulated within said skin layer.

THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:-

1. A device for communicating electric signals across the skin layer of a patient, wherein said device includes: an electrically conductive core made from a single piece of magnetic material capable of forming an EMF flux loop; first and second coils, which are in EMF communication with said electrical conductive core and wherein said first coil is positioned externally to said patient and surrounds at least a first portion of said electrically conductive core; and said second coil is implanted beneath or in said skin layer and surrounds at least a second portion of said electrically conductive core.

2. The device as claimed in claim 1, wherein said electrically conductively core is implanted at least partially within said skin layer.

3. The device as claimed in claim 1, wherein said electrically conductively core is formed in a loop or ring-like configuration.

4. The device as claimed in claim 3, wherein said electrically conductively core does not breach an outer surface of said skin layer.

5. The device as claimed in claim 1, wherein said device includes a sleeper ring to interact with said first coil.

6. The device as claimed in claim 1, wherein said device includes a textured surface on at least a portion of said electrically conductively core.

7. The device claimed in claim 1, wherein said electrically conductive core is encapsulated within said skin layer.

8. The device as claimed in claim 1, wherein said device includes a layer of protective material surrounding at least a portion of the electrically conductive core.